K020894

510(k) Submission for Mission Diagnostic Reagents on pH/Blood Gas &/or Electrolyte Analyzers

1. **Submitter's Name & Address**

Mission Diagnostics
331 Fiske St
Holliston MA 01746
FAX: 508-429-0452

Contact Person:
Linda Stundtner
QA/RA Manager
508-429-0450

Establishment Registration Number: In Process

Date of Preparation: March 18, 2002

2. **Identification of the Device:**

Proprietary/Trade name:	Calibrating Material, Cal-Pak, Buffers
Common or usual name	Calibrators for ISE and/or pH/Blood Gas automated systems
Classification name:	Calibrator, secondary
Device Classification	II
Regulation Number:	21 CFR § 862.1150
Panel:	Chemistry (75)
Product Code:	JIT

- Mission manufactures calibrators intended to serve as direct replacements to like named products manufactured by Original Equipment Manufactures (OEM)

3. **Predicate Device:**

- Mission claims substantial equivalence to the OEM Calibrating Materials listed below:

Mission Product	OEM Equivalent
AV-BP0136D Type 1 Buffer 7.383	BP0136 Type 1 Buffer 7.383 AVL
AV-BP0137D Type 2 Buffer 6.841	BP0137 Type 2 Buffer 6.841 AVL
CD-473691AD Cal-Pak for Ciba-Corning 238	473691 pH/Blood Gas pH 7.38 Cal
CD-473496AD Cal-Pak for Ciba-Corning 248	473496 6.8/7.3 Buffer for 248
CD-104227AD Cal-Pak for Ciba-Corning 348	104227 6.8/7.3 Buffer for 348
CD-478855D Ciba-Corning 200 Series 7.3 Buffer	478855D Ciba-Corning 200 Series 7.3
CD-478856D Ciba-Corning 200 Series 6.8 Buffer	478856D Ciba-Corning 200 Series 6.8
CD-478864D Ciba-Corning 664 Cal/Wash	478864D Ciba-Corning 664 Cal/Wash
CD-478865D Ciba-Corning 664 Slope	478865D Ciba-Corning 664 Slope
CD-473385D Bayer 800 Series 7.3/Co-ox Zero	473385D Bayer 800 Series 7.3/Co-ox Zero
CD-473386D Bayer 800 Series 6.8 Buffer	473386D Bayer 800 Series 6.8 Buffer
CD-473387D Bayer 800 Series Wash/Cal G/L Zero	473387D Bayer 800 Series Wash/Cal G/L Zero
CD-570096D Bayer 800 Series Cal G/L	570096D Bayer 800 Series Cal G/L

- The OEM products for Ciba-Corning Instruments (238, 248, 348, 664, & 200 Series) were originally released under the Ciba-Corning name. The company has under gone several owner and name changes: starting out as Corning Glass, Ciba-Corning, Chiron, and lastly

Bayer. For the purposes of this 510(k) the OEM for theses products will be referred to as Ciba-Corning.

- The OEM products for Bayer Instrument (800 Series (aka RapidLab) were originally released under the Chiron name. The company has under gone several owner and name changes: starting out as Corning Glass, Ciba-Corning, Chiron, and lastly Bayer. For the purposes of this 510(k) the OEM for theses products will be referred to as Bayer.

4. Device Description:

- The Calibrators for the OEM Instruments are aqueous reagents with salts added to obtain desired analyte levels to provide calibration of the electrodes and rinse the sample path.

- **Intended Use**:

- The reagents are intended for use on equivalent OEM Instruments.

- The original equipment manufacturer (OEM) of the instruments and the predicate reagents which are necessary for the continued operation and use of the instruments.

- Mission uses a similar composition, description and packaging as that used by the OEM in its products, as shown in the packaging section of this submission.

- Performance equivalence is shown in the following manner:

  - Through a method comparison where results obtained on an equivalent OEM analyzer, calibrated with Mission calibrating material are compared with results obtained on the same analyzer calibrated with OEM calibrating material.

  - A summary of the results of these studies follows:

5. Performance Characteristics:

Precision Data

Precision data are collected from the analysis of three levels of control materials tested over a minimum of 7 days on each OEM analyzer. Analyzers are calibrated with Mission reagents and alternately with the OEM reagents for testing.

Precision Data Table - 238 Ciba-Corning pH/BG Analyzer

Instr	238

pH

	Mission					
Level	N	Mean	Stdev	Min	Max	% CV
QC1	9	7.15	0.01	7.15	7.16	0.1%
QC2	9	7.41	0.01	7.40	7.44	0.2%
QC3	9	7.64	0.01	7.63	7.65	0.1%

Instr	238

pO2

	Mission					
Level	N	Mean	Stdev	Min	Max	% CV
QC1	9	63	1	62	64	1.2%
QC2	9	101	2	98	103	1.6%
QC3	9	158	6	151	169	3.7%

Instr	238

pCO2

	Mission					
Level	N	Mean	Stdev	Min	Max	% CV
QC1	9	81	2	77	83	2.7%
QC2	9	45	1	44	46	1.6%
QC3	9	18	0	18	19	2.4%

Precision Data Table - 248 Ciba-Corning pH/BG Analyzer

Instr	248

pH

	Mission					
Level	N	Mean	Stdev	Min	Max	% CV
QC1	10	7.156	0.003	7.151	7.160	0.0%
QC2	10	7.403	0.003	7.397	7.407	0.0%
QC3	10	7.630	0.005	7.622	7.639	0.1%

Instr	248

pO2

	Mission					
Level	N	Mean	Stdev	Min	Max	% CV
QC1	10	53.9	2.5	51.6	59.7	4.6%
QC2	10	94.9	1.1	93.0	96.9	1.1%
QC3	10	160.8	3.3	157.2	167.7	2.1%

Instr	248

pCO2

	Mission					
Level	N	Mean	Stdev	Min	Max	% CV
QC1	10	77.3	1.0	76.3	79.7	1.3%
QC2	10	47.0	0.4	46.6	47.8	0.8%
QC3	10	21.8	0.2	21.5	22.0	0.7%

Precision Data Table - 248 Ciba-Corning pH/BG & Electrolyte Analyzer

Instr	348

Na

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	21	113	2.0	110	118	1.8%
QC2	21	139	2.7	135	147	1.9%
QC3	20	162	2.4	158	169	1.5%

Instr	348

K

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	21	2.10	0.02	2.06	2.13	0.8%
QC2	21	4.38	0.06	4.16	4.43	1.3%
QC3	21	6.88	0.08	6.74	7.01	1.2%

Instr	348

Ca

	Mission					
Level	N	Mean	StdDev	Min	Max	%CV
QC1	21	2.06	0.08	1.75	2.13	4.1%
QC2	21	1.16	0.06	0.94	1.25	5.4%
QC3	21	0.58	0.06	0.44	0.65	10.4%

Instr	348

pH

	Mission					
Level	N	Mean	Stdev	Min	Max	%CV
QC1	10	7.166	0.006	7.154	7.177	0.1%
QC2	10	7.442	0.019	7.418	7.476	0.3%
QC3	10	7.669	0.027	7.634	7.717	0.4%

Precision Data Table - 664 Ciba-Corning Analyzer

Instr	664

Na

	Mission					
Level	**N**	**MEAN**	**stdev**	**Min**	**Max**	**% CV**
QC1	16	112.0	1.4	110.0	114.9	1.3%
QC2	16	137.6	0.9	136.8	139.4	0.6%
QC3	16	162.3	1.0	161.1	164.4	0.6%

Instr	664

K

	Mission					
Level	**N**	**Mean**	**Stdev**	**Min**	**Max**	**% CV**
QC1	16	1.98	0.03	1.95	2.04	1.3%
QC2	16	4.38	0.04	4.34	4.46	0.9%
QC3	16	6.99	0.07	6.92	7.14	1.0%

Instr	664

Cl

	Mission					
Level	**N**	**Mean**	**Stdev**	**Min**	**Max**	**% CV**
QC1	16	83	4.6	77	99	5.6%
QC2	16	99	7.9	91	127	8.0%
QC3	16	122	9.4	88	127	7.7%

Instr	664

tCO2

	Mission					
Level	**N**	**Mean**	**Stdev**	**Min**	**Max**	**% CV**
QC1	16	28.8	1.3	26.3	31.1	4.6%
QC2	16	30.4	1.3	28.4	32.3	4.2%
QC3	16	23.3	0.8	21.9	24.8	3.6%

Precision Data Table - 288 Ciba-Corning pH/BG & Electrolyte Analyzer

Instr	288

Na

	Mission					
Level	**N**	**Mean**	**Stdev**	**Min**	**Max**	**% CV**
QC1	19	108.0	0.8	107.0	110.0	0.7%
QC2	19	134.3	0.7	132.7	135.7	0.5%
QC3	19	159.2	1.0	157.3	160.7	0.6%

Instr	288

K

	Mission					
Level	**N**	**Mean**	**Stdev**	**Min**	**Max**	**% CV**
QC1	19	1.66	0.02	1.63	1.69	1.1%
QC2	19	4.25	0.02	4.22	4.29	0.6%
QC3	19	7.07	0.04	7.02	7.14	0.6%

Instr	288

Ca

	Mission					
Level	**N**	**Mean**	**Stdev**	**Min**	**Max**	**% CV**
QC1	19	2.13	0.03	2.03	2.18	1.6%
QC2	19	1.12	0.01	1.09	1.14	1.0%
QC3	18	0.48	0.01	0.45	0.51	2.8%

Instr	288

pH

	Mission					
Level	**N**	**Mean**	**Stdev**	**Min**	**Max**	**% CV**
QC1	25	7.182	0.012	7.166	7.210	0.2%
QC2	25	7.426	0.012	7.403	7.455	0.2%
QC3	25	7.651	0.005	7.645	7.661	0.1%

Correlation with OEM Reagents

Correlation data for electrolytes on the 348 were obtained from human serum samples for Na, K, Cl, Ca. Samples are spiked with Human Serum Albumin to yield varying concentrations of each of the measuring analytes. The serum samples were measured on the 348 analyzer calibrated with Mission reagents for 1 run and 1 comparison run with OEM reagents each test day.

Correlation for pH were obtained by comparing 3 levels of QC.

Linear regression analysis was performed using Mission data as the independent X variable and Corning as the dependent Y variable in the equation $Y = mX + b$

Correlations demonstrated slopes of 1 and R^2 's of 0.99, which support a claim of substantial equivalence. Graphs of Correlation are in Attachment Section.

Regression Analysis of Mission vs OEM; Human Serum Results

Y = mX + b where Y = OEM results, X = Mission results, m = Slope, b = Intercept

Na

	N	Slope	Interecept	R^2	Range
348	44	1.02	-0.96	0.99	103 - 185
288	19	0.95	8.88	1.00	103 - 171
664	25	0.95	6.57	1.00	93 - 173

K

	N	Slope	Interecept	R^2	Range
348	49	1.00	0.05	1.00	2.39 - 5.87
288	44	1.04	-0.06	1.00	1.54 - 6.59
664	44	1.02	-0.04	1.00	1.82 - 6.56

Ca

	N	Slope	Interecept	R^2	Range
348	35	0.96	0.07	0.99	0.94 - 2.11
288	44	1.00	-0.05	0.99	0.94 - 2.48

Cl

	N	Slope	Interecept	R^2	Range
664	25	1.11	-10.7	1.00	81 - 137

Regression Analysis of Mission vs OEM; QC Results

Y = mX + b where Y = OEM results, X = Mission results, m = Slope, b = Intercept

pH

	N	Slope	Interecept	R^2	Range
238	30	1.00	0.03	1.00	7.15 - 7.65
248	30	1.01	-0.06	1.00	7.151 - 7.639
348	30	1.00	-0.01	0.99	7.151 - 7.717
288	21	0.98	0.17	1.00	7.163 - 7.661

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms Linda Stundtner
QA/RA Manager
Diamond Diagnostics Inc.
Mission Diagnostics
333 Fiske Street
Holliston, MA 01746

APR 2 9 2002

Re: k020894
Trade/Device Name: Mission Diagnostic Reagents for pH/BG &/or Electrolyte Analyzers
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: March 18, 2002
Received: March 19, 2002

Dear Ms. Stundtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k(Number K020894

Device Name: Mission Diagnostic Reagents for pH/BG &/or Electrolyte Analyzers

Indication For Use:

The products encompassed by this request are intended for in-vitro diagnostics use and are intended for use in calibrating the electrodes and flushing the sample flow path of the equivalent OEM Analyzers.

Mission Product PN	OEM Instrument(s) Used on
AV-BP0136D Type 1 Buffer 7.383	AVL 99X and Compact Analyzers
AV-BP0137D Type 2 Buffer 6.841	AVL 99X and Compact Analyzers
CD-473691AD Cal-Pak for Ciba-Corning 238	Ciba-Corning 238 pH/BG Analyzer
CD-473496AD Cal-Pak for Ciba-Corning 248	Ciba-Corning 248 pH/BG Analyzer
CD-104227AD Cal-Pak for Ciba-Corning 348	Ciba-Corning 348 pH/BG & Electrolyte Analyzer
CD-478855D Ciba-Corning 200 Series 7.3 Buffer	Ciba-Corning 200Series pH/BG Analyzer
CD-478856D Ciba-Corning 200 Series 6.8 Buffer	Ciba-Corning 200 Series pH/BG Analyzer
CD-478864D Ciba-Corning 664 Cal/Wash	Ciba-Corning 664 Analyzer
CD-478865D Ciba-Corning 664 Slope	Ciba-Corning 664 Analyzer
CD-473385D Bayer 800 Series 7.3/Co-ox Zero	Bayer 800Series Analyzers
CD-473386D Bayer 800 Series 6.8 Buffer	Bayer 800Series Analyzers
CD-473387D Bayer 800 Series Wash/Cal G/L Zero	Bayer 800Series Analyzers
CD-570096D Bayer 800 Series Cal G/L	Bayer 800Series Analyzers

Mission reagents are intended to serve as direct replacements to like named products manufactured by the OEM.

The products encompassed are to be handled using normal laboratory precautions.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrance of CDRH, Office of the Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020894

Prescription Use X
(Per 21 CFR 801.109)

(Optional format 3-10-98)